K001948

HYPERTENSION DIAGNOSTICS™ inc.

Predicting Your CardioVascular Health Non-Invasively

NOV - 1 2000

510(k) SUMMARY

General Information

Submitter's Name:	Hypertension Diagnostics, Inc.
Address:	2915 Waters Road – Suite 108 Eagan, MN 55121-1562
Telephone:	651-687-9999
Contact Person:	Dr. Charles F. Chesney, Executive Vice President and C.T.O.
Registration Number:	2134830

Device

Name:	CVProfilor™ DO-2020 CardioVascular Profiling System
Trade Name:	CVProfilor™ DO-2020 CardioVascular Profiling System
Common Name:	Non-Invasive Blood Pressure Measurement and Waveform Profiling System
Classification Name:	Non-Invasive Blood Pressure Measurement System
Product Code:	DXN
Class:	II
Regulation Number:	21 CFR 870.1130

Identification of Legally Marketed Devices

Name:	MS-2000
K Number:	K961144

Description of the Device

The CVProfilor™ DO-2020 CardioVascular Profiling System can be used by health care professionals to measure blood pressure values (systolic, diastolic and mean arterial pressure) and pulse rate. The DO-2020 calculates pulse pressure, body surface are (BSA), and body mass index, (BMI) and provides indications of arterial compliance. The indications of arterial compliance (elasticity indices) can be used as an initial screening device to determine if patients have potential underlying vascular disease that might require more specific diagnostic evaluations by physicians or other health care providers.

The CVProfilor™ DO-2020 CardioVascular Profiling System consists of: (a) the DO-2020 Instrument enclosure with adjustable handle/stand; (b) an arterial pulse pressure (waveform) sensor (with cable assembly) attached to a sensor holding and positioning apparatus; (d) wrist stabilizer; (e) blood pressure cuffs (in small, regular and large adult sizes); (f) ink-jet printer and black ink cartridge; and (g) electrical power cords and data cables. The DO-2020 Instrument includes a microprocessor computer, main electronics board, electroluminescent touch-screen display, oscillometric blood pressure module, electrical power supply and a resident set of proprietary and patented software programs.

Intended Use Statement

"The CVProfilor™ DO-2020 CardioVascular Profiling System can be used by health care professionals to measure blood pressure values (systolic, diastolic and mean arterial pressure) and heart pulse rate. The DO-2020 calculates pulse pressure, body surface area (BSA) and body mass index (BMI), and provides indications of arterial compliance. The indications of arterial compliance (elasticity indices) can be used as an initial screening device to determine if patients have potential underlying vascular disease that might require more specific diagnostic evaluations by physicians or other health care providers."

Device Performance

The CVProfilor™ DO-2020 CardioVascular Profiling System was evaluated relevant to environmental, packaging shipment, electrical, mechanical, electromagnetic compatibility, and intra-/inter-instrument variability.

Hypertension Diagnostics, Inc. also obtained clinical data to demonstrate that the CVProfilor™ DO-2020 CardioVascular Profiling System identifies expected changes in vascular compliance (that is, arterial elasticity) that would indicate the possibility of underlying vascular disease. A prospective, controlled clinical study was conducted which involved a total of 235 subjects being seen as outpatients for hypertension screening as well as normal volunteers. The clinical study volunteers and patients meeting inclusion/exclusion criteria and having executed an informed consent form were assigned to one of four categories or study groups based on their hypertension status, family history of hypertension, and whether or not medication was controlling high blood pressure.

The results from the clinical study demonstrated that the CVProfilor™ DO-2020 Cardio-Vaascular Profiling System identifies the expected differences in vascular compliance (that is, arterial elasticity) that would indicate the possibility of underlying vascular disease.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 1 2000

Hypertension Diagnostics™, Inc.
c/o Charles F. Chesney, D.V.M., Ph.D., R.A.C.
Executive Vice President and
Chief Technology Officer
2915 Waters Road
Suite 108
Eagan, MN 55121-1562

Re: K001948
Trade Name: CV Profiler DO-2020 Cardiovascular Profiling System
Regulatory Class: II (two)
Product Code: DXN
Dated: October 16, 2000
Received: October 17, 2000

Dear Dr. Chesney:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use Statement/Form

Ver/ 3 – 4/24/96

Applicant: HYPERTENSION DIAGNOSTICS, INC. (Eagan, MN)

510(k) Number (if known): K001948

Device Name: CVProfilor™ DO-2020 CardioVascular Profiling System

Indications For Use:

The CVProfilor™ DO-2020 CardioVascular Profiling System can be used by health care professionals to measure blood pressure values (systolic, diastolic and mean arterial pressure) and the heart pulse rate. The CVProfilor™ DO-2020 System calculates pulse pressure, body surface area (BSA) and body mass index (BMI), and provides indications of arterial compliance. The indications of arterial compliance (that is, elasticity indices) can be used as an initial screening device to determine if patients have potential underlying vascular disease that might require more specific diagnostic evaluations by physicians or other health care providers.

The CVProfilor™ DO-2020 System is indicated for use with patients of both genders who are at least fifteen (15) years of age or older. Patients should be ambulatory and not have a diagnosis of heart failure, arrythmia or cardiac valve abnormality (that is, aortic stenosis or mitral regurgitation).

Division of Cardiovascular & Respiratory Devices
510(k) Number K001948

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Presciption Use X – or – Over-the-Counter Use ____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)